



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

OCT 10 2000

7107 '00 OCT 13 A9:35

Armand Lione, Ph.D.  
President  
Associated Pharmacologists & Toxicologists  
4007 Connecticut Avenue, N.W.  
Washington, DC 20008

Re: Docket No. 83P-0187/CP3

Dear Dr. Lione:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated April 24, 2000, asking FDA to withdraw approval of the Today Contraceptive Sponge because of the increased risk of toxic shock syndrome and infection with the human immunodeficiency virus.

FDA has been unable to reach a decision on your petition because it raises significant issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,

Janet Woodcock, M.D.  
Director  
Center for Drug Evaluation and Research

83P-0187

LET 7